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Cameron K. Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER	
LIN, JAMES	

ART UNIT	PAPER NUMBER
1762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,316	HOSSAINY ET AL.	
	Examiner	Art Unit	
	Jimmy Lin	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-64* is/are pending in the application.

4a) Of the above claim(s) *3,6,7,11,12,14,17,20,23,34,41,48 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,8-10,13,15,16,18,19,21,22,24-33,35-40,42-47,49-58 and 60-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 3, 6, 7, 11, 12, 14, 17, and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/21/2006.

2. Newly submitted claim 58 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: modifying the balloon from a hyper-inflated state to a state of intended expanded configuration is essentially partially inflating the balloon, which is a species of reducing the balloon to a deflated state or the collapsed state (species 3 in the Election/Restriction requirement filed 4/5/2006).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the limitation of modifying a balloon from a hyper-inflated state to a state of intended expanded configuration of claim 58 is withdrawn from consideration as being directed to a non-elected species. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

3. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The term "hyper-inflated state" does not further limit the limitation of "wherein the inflated state is greater than a range of an intended expanded configuration of the balloon and less than a diameter or size at which the balloon becomes damaged or unsuitable for its intended use" as required by claim 1.

4. Claim 15 is objected to because of the following informalities: the phrase of "applying a substance to an outer surface of the balloon, wherein the substance is coated on the outer surface of the balloon and/or is deposited within a wall membrane of the balloon" is repetitive. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 15, 21-31, 47-56, and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support for reducing the balloon to a collapsed configuration or an under inflated state or deflating the balloon in general in preparation for the intended use of the balloon (claims 15 and 21). The specification only provides support for reducing the balloon size during the modification process or during/prior to the drying process.

There is no support for deflating the balloon after removal of at least some of the fluid. The specification only provides support for deflating the balloon prior to or during the process of removal of the fluid.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 10, 13, and 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Kokish (6,544,223).

Claim 13: Kokish teaches a partially inflated balloon of a catheter (col. 6, lines 56 – 61) and coating the outer surface of the balloon with a polymer solution and a second solution (col. 7, lines 8 – 15). A polymer solution is sprayed onto the balloon of a catheter and is allowed to air dry (col. 7, lines 8 – 28). Once the fluid carrier is removed from the balloon, a dry form of the substance would inherently be left on the outer surface of the balloon. The inflated state is maintained at the same level during the drying process.

Claim 10: The balloon is completely deflated to a flattened configuration prior to the removal of the fluid carrier (Example 2).

Claim 39: The balloon must necessarily be at least partially inflated in order to later completely deflate. Therefore, the balloon must be least partially inflated prior to deposition.

Claim 40: Kokish does not teach that the inflated state of the balloon is changed during the deposition step. Therefore, the inflated state must be maintained at the same or generally the same level during the deposition step.

9. Claims 13, 15, 21, 24-26, 28-29, 31, 43-44, 46, 50-52, 54, 56, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al. (U.S. Publication 2002/0037358).

Claim 13: Barry discloses a method of modifying a balloon catheter, the method comprising:

inflating a balloon of a catheter to an inflated state;

applying paclitaxel (i.e., a therapeutic drug) in a fluid carrier onto the polyurethane membrane of the balloon catheter;

drying the fluid carrier from the balloon leaving a dry form of the paclitaxel on the surface of the balloon (Example 9).

Barry does not teach inflating or deflating the balloon during the deposition or drying process. Therefore, the inflated state of the balloon must be maintained at the same or generally the same level during the drying step.

Claims 15,21: Barry teaches that the balloon is in its substantially deflated state prior to insertion into a patient (i.e., deflating balloon to a collapsed configuration or an under inflated

state in preparation for the intended use of the balloon) ([0046]; Fig. 1b). Paclitaxel is applied onto the outer surface of a balloon to deposit paclitaxel within the polyurethane coating of the balloon (i.e., within the wall membrane of the balloon (Examples 9; [0032]).

Claims 25-26,43-44,51-52: Paclitaxel is saturated (i.e., dissolved) in the carrier fluid.

Claim 28: Paclitaxel is a drug.

Claims 24,50,63: Barry does not teach inflating or deflating the balloon during the deposition step. Therefore, the inflated state of the balloon must be maintained at the same or generally the same level during the deposition step.

Claims 29,54: The Applicant teaches that polyurethane is one of the preferred porous materials used as the wall membrane (pg. 6). Therefore, the polyurethane membrane of Barry must necessarily be a porous material.

Claims 31,46,56: The balloon is inflated prior to deposition.

10. Claims 13, 21, 24, 28-29, 31, 41, 46, 57, 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Reiss et al. (U.S. Publication 2003/0032963).

Claim 57: Reiss discloses a method for coating a balloon. The balloon can have a catheter [0050]. The balloon can be wholly inflated before applying a therapeutic drug to coat the balloon [0201]. The balloon can be deflated and then allowed to dry [0203].

Claims 21,60: The balloon is deflated prior to drying. The coated balloon is then ready for packaging for use by the surgeon [0203].

Claims 13,24,63: Reiss does not teach that the inflated state of the balloon is changed during the coating process. Therefore, the inflated state of the balloon must necessarily be maintained at the same or generally the same level during the coating step.

Claims 23,41,59: The balloon can be wholly inflated.

Claim 28: The substance can be a therapeutic drug.

Claim 29: The balloon can be made of nylon [0067]. The Applicant teaches that nylon is one of the preferred porous materials used as the wall membrane (pg. 6).

Claims 31,46: The balloon is inflated prior to coating.

11. Claims 13, 21, 24, 28, 31, 46, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al. (U.S. Patent 5,674,192).

Claims 13,21,24,28,31,46: Sahatjian discloses a method for coating a balloon of a catheter. The balloon is inflated, coated with a drug, dried, and then deflated. The drug is in a carrier fluid (col. 14, lines 45-63). The drug can be a therapeutic drug (col. 5-6). Sahatjian does not teach that the inflated state of the balloon is changed during the coating process. Therefore, the inflated state of the balloon must necessarily be maintained at the same or generally the same level during the coating step.

Claim 64: The balloon is deflated after drying (i.e., after removal of at least some of the carrier fluid).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 1, 4-5, 8-10, 15, 19, 22, 32-35, 39-40, 42, 47-50, 54, 56, 58-59, 61-62, 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss '963, as applied to claims 13, 21, and 57 above.

Claims 10,15,32,59,61: Reiss does not explicitly teach that the balloon can be deflated to a collapsed or under inflated state. However, Reiss does teach that the balloon is

ready for packaging after deflating the balloon [0203]. The deflated state is not explicitly taught and, thus, is only a generic teaching for deflation. When packaging the balloons, a completely deflated balloon would take up the least amount of space, thereby being able to package more balloons in a box having finite size. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have completely deflated the balloon of Reiss for packaging. One would have been motivated to do so in order to have maximized the space in a box.

Claims 1,4,22,35,42,47,49,62: Reiss teaches that the balloon can be wholly inflated, but does not explicitly teach that the inflated state is greater than a range of an intended expanded configuration of the balloon and less than a diameter at which the balloon becomes damaged or unsuitable for use. However, an inflated state greater than a range of an intended configuration can be interpreted to be having one extra molecule of fluid more than an inflated state at its intended expanded configuration. A *prima facie* case of obviousness exists where the claimed ranges and prior art do not overlap but are close enough that one in ordinary skill in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 f.2d 775, 227 USPQ 773 (Fed. Cir. 1985). See MPEP 2144.05. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have inflated the balloon to an inflated state greater than a range of an intended expanded configuration as opposed to the wholly inflated state of Reiss with a reasonable expectation of success because the state of inflations are so close that one of ordinary skill in the art would have expected the balloons to have similar properties, especially in the absence of unexpected results. In addition, it would have been obvious to one of ordinary skill in the art at the time of invention to have inflated the balloon so that the balloon does not become damaged or unsuitable for its intended use of insertion into a patient because a consumer would be unlikely to purchase a damaged or unsuitable balloon and because such unsuitability would defeat the intended purpose of the balloon catheter used for insertion into a patient.

Claim 5,40,50: Reiss does not teach that the inflated state of the balloon is changed during the coating process. Therefore, the inflated state of the balloon must necessarily be maintained at the same or generally the same level during the coating step.

Claim 8: The therapeutic drug is in a carrier fluid.

Claim 9: After drying, a dry form of the substance will be left on balloon.

Claims 19,39,56: The balloon is inflated prior to the coating step.

Claims 33,64: Reiss does not explicitly teach that the balloon can be reduced to a deflated state or to a collapsed configuration during the drying process or after the removal of at least some of the carrier fluid. However, Reiss does teach that the balloon can be deflated prior to drying. The selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. See, for instance, *In re Burhans,* 154 F.2d 690, 69 USPQ 330 (CCPA 1946) and MPEP 2144.04.II.C. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have deflated the balloon during the drying process or after the removal of at least some of the carrier fluid as opposed to deflating the balloon prior to drying with a reasonable expectation of success because the Applicant has not provided any evidence showing that the order of performing the process steps has new or unexpected results.

Claims 34,48: The balloon can be wholly inflated.

Claim 54: The balloon can be made of nylon [0067]. The Applicant teaches that nylon is one of the preferred porous materials used as the wall membrane (pg. 6).

Claim 58: Reiss does not explicitly teach hyper-inflating the balloon or that the balloon can be deflated to a collapsed or under inflated state, but such is obvious as discussed above.

15. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss '963, as applied to claim 1 above, in view of Fukaya '066.

Reiss is discussed above, but does not explicitly teach that gas is blown subsequent to deposition. Reiss does teach the need to dry the coating after deposition.

Fukaya teaches a method of coating a balloon catheter, wherein the balloon is blow-dried after deposition of the coating (col. 27, lines 54-64). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have included a step of blow-drying in the drying process of Reiss with a reasonable expectation of

success because Fukaya teaches that blow-drying is a suitable method of drying a coating on a balloon catheter. In addition, one would have been motivated to do so in order to evaporate the solvent in a shorter time.

16. Claims 27, 45, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '358, as applied to claims 13, 15, and 21 above, in view of Reiss (U.S. Patent 6,913,617).

Barry is discussed above, but does not explicitly teach that paclitaxel is supersaturated in the carrier fluid.

Reiss teaches that a method of coating an implantable device (i.e., a balloon catheter), wherein a mixture of a therapeutic substance and a carrier fluid can be coated onto the device. The therapeutic substance can be supersaturated in the carrier fluid (col. 9, lines 11-25). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have coated the balloon catheter of Barry with a supersaturated solution of paclitaxel in a carrier fluid with a reasonable expectation of success because Reiss teaches that coating a supersaturated solution of a therapeutic device is suitable in the art of implantable medical devices.

17. Claims 25-27, 36-38, 43-45, and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss '963, as applied to claims 10, 13, 15, 21 above, view of Reiss '617.

Reiss '963 teaches that the therapeutic drug can be in a carrier fluid [0201], but does not explicitly teach that the therapeutic drug can be dissolved, saturated, or supersaturated in the carrier fluid. However, such a modification is obvious over Reiss '617 for substantially the same reason as discussed above.

18. Claims 30 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry '617, as applied to claim 15 and 21 above, view of Boulais (U.S. Publication 2004/0213893).

Barry teaches that a polyurethane coating (i.e., a porous membrane) can be deposited on the surface of the balloon, but does not explicitly teach an inner non-porous layer and an outer porous layer.

Boulais teaches that a balloon catheter can be coated with multiple layers of different polymer materials, such as polyurethanes and polylactic acid (i.e., a non-porous material) [0008]-[0009]. The Applicant teaches that polylactic acid is one of the preferred non-porous materials used as the wall membrane (pg. 7, 1st full paragraph). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have had an inner polylactic acid layer and an outer polyurethane layer on the balloon surface of Barry with a reasonable expectation of success because Boulais teaches that multiple layers of different polymer materials can be coated on the surface of a balloon catheter and that such polymers are suitable materials for coating a balloon catheter.

Response to Arguments

19. Applicant's arguments filed 9/18/2006 have been fully considered but they are not persuasive.

Claims 1, 5, 8-10, 13, 15-16, and 19 as anticipated by Kokish '223:

The Applicant argues that Example 2 of Kokish only teaches that the balloon is completely deflated to a flattened configuration, but does not teach inflating a balloon which is later deflated prior to or during the drying process. However, the balloon must have been in an inflated state greater than the completely deflated state prior to completely deflating the balloon. Therefore, the balloon must have necessarily been at least partially inflated so that the balloon can later be completely deflated. In addition, the balloon is deflated prior to the drying process because the deflation step takes place before the deposition process, which takes place before the drying process.

The Applicant argues that Kokish fails to teach "wherein the inflated state is maintained at the same or a generally same level during the removal of the fluid carrier". The Applicant further argues that Kokish simply teaches that the balloon is partially inflated during the drying

process and that being partially inflated during the drying process is not equivalent to a claimed limitation that the inflated state is maintained at the same or generally same level. However, Kokish teaches that the balloon is suspended from a fixture and is partially inflated (col. 6, lines 56-61). The balloon is then rotated about its axis while maintaining the balloon in its partially inflated configuration during the coating process (col. 7, lines 8-15). Finally, the balloon is allowed to dry with the balloon partially inflated (col. 7, lines 23-26). Kokish seems to emphasize that the balloon remains partially inflated during the entire process and never teaches deflating or further inflating the balloon during the process in Example 1. Therefore, the inflated state of the balloon is maintained at generally the same level during the removal of the fluid carrier.

The Applicant traverses the rejection of claim 15. However, the Applicant has changed the scope of claim 15 with the current amendments and new rejections have been made.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is 571-272-8902. The examiner can normally be reached on Monday thru Friday 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL

TIMOTHY MEEKS
SUPERVISORY PATENT EXAMINER